

### **REMARKS**

Claims 1-14 were previously cancelled. Applicants reserve the right to file additional applications directed towards the cancelled subject matter. Claims 15, 16, 17 and 26 are currently amended. Support for the amendments can be found throughout the specification, specifically at paragraph [0027], Examples 1 and 2 and the claims as originally filed. No new matter has been added.

### **Information Disclosure Statement**

The Examiner states that the listing of references in the specification is not a proper Information Disclosure Statement. Office Action page 2. All references cited on pages 1 and 2 of the specification were submitted to the United States Patent and Trademark Office in an Information Disclosure Statement (IDS) on June 13, 2005. All of the references which were cited by the Examiner on form PTO-892 were forwarded to the Applicants' representative with the current Office Action. In addition, the Examiner acknowledged receipt of the IDS on the Office Action Summary also included with the current Office Action. Applicants' respectfully submit that all references listed in the specification have been properly submitted to the Patent and Trademark Office. Withdrawal of the rejection is respectfully requested.

### **Objections to the Specification**

The Examiner has objected to the abstract. Office Action page 3. The abstract has been amended to correct the informalities cited by the Examiner. The Examiner has objected to informalities in the specification. Office Action pages 2-3. The specification has been amended to add a brief description of the drawings and to amend the paragraph starting at page 6, line 28, as suggested by the Examiner. Withdrawal of the objections is respectfully requested.

### **Rejections Under 35 U.S.C. §102(e)**

Claims 15, 17-18, 21-22, and 25-26 are rejected under 35 U.S.C. §102(e) as being anticipated by Hanna (U.S. Patent No. 6,440,337; hereinafter "Hanna '337"). The Examiner states that Hanna teaches all of the limitations of the present invention. Office

Action pages 3-4. Applicants respectfully traverse the rejection.

Newly amended claim 15 now requires that an additional antisolvent is admixed at least one second after completion of step (a) and after the precipitated particles have grown to a volume weighted average diameter of at least 0.1  $\mu\text{m}$ . As described in the Hanna specification:

In the present method, the degree of supersaturation in the mixing zone is advantageously maintained at a relatively low level so as to prevent premature nucleation. The level of supersaturation can suitably be raised subsequently in the nucleation zone by adding additional antisolvent. Thus, the speed of nucleation may be increased without significantly affecting particle size distribution.

Specification, paragraph [0012]

In order to achieve uniform particle growth without significant occurrence of additional nucleation, the extra antisolvent is admixed after the precipitated particles have grown to a volume weighted average diameter of at least 0.1  $\mu\text{m}$ .

Specification, paragraph [0027].

In contrast, Hanna teaches a process in which a first supercritical fluid, a solution or suspension of a substance in a vehicle and an impinging flow of a second supercritical fluid are simultaneously introduced in a particle formation chamber (see claim 1). Hanna teaches:

The solution/suspension can be subjected to a very high degree of dispersion due to the high overall supercritical fluid velocity (i.e., high overall kinetic energy), and its efficient dispersion, at substantially the same time as the vehicle is extracted from it, in turn can provide a high degree of uniformity in the particles formed. (Emphasis added).

Col. 2, lines 33-38.

The outlets of the primary nozzle passages should be reasonably close to that of the secondary nozzle passages, again so as to maximize kinetic energy transfer between the second supercritical fluid and the solution/suspension. (Emphasis added).

Col. 6, lines 33-38.

In addition, the Figures included with the Hanna publication, notably Figures 2 and 5-9, clearly teach the almost instantaneous combination of the impinging flow of the second supercritical fluid with the first supercritical fluid and the solution/suspension in the particle formation chamber. To anticipate, a prior art reference "must disclose each and every feature of the claimed invention, either explicitly or inherently." *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047 (Fed. Cir. 1995). The subject matter of amended claim 15 is clearly not anticipated by Hanna as the reference fails to disclose a process in which a second supercritical fluid is admixed with the first supercritical fluid and the solution/suspension at least one second after the first supercritical fluid and the solution/suspension have been combined and after precipitated particles have grown to a volume weighted average diameter of at least 0.1  $\mu\text{m}$ . Hanna clearly does not disclose each and every element of amended claim 15 or those claims depending from claim 15. Applicants respectfully request withdrawal of the rejection.

#### **Rejections Under 35 U.S.C. §103(a)**

##### **Hannah '337**

Claims 16, 19-20, and 23-24 are rejected under 35 U.S.C. §103(a) as being unpatentable over Hanna '337. The Examiner states that Hanna '337 teaches all the elements of these claims with the exception of (a) the limitations regarding addition of the additional antisolvent after the growth of the precipitated particles to a volume weighted average diameter of at least 0.1  $\mu\text{m}$ ; (b) the collected particles containing at least 1% (wt vol) solvent; (c) mixing of the additional antisolvent to reduce the solvent content of the collected particles to less than 1% (wt vol); (d) the mixing energy exceeds 1 J/kg; and (e) the residence time within the nucleation growth zone is at least 3 seconds. The Examiner concludes that one of ordinary skill in the art would have been motivated to alter the teaching of the Hanna '337 reference because discovering optimum or workable ranges involves only routine skill in the art. Office Action pages 5-8.

Applicants respectfully traverse the rejection. The recently revised Examiner guidelines for assessing obviousness set forth detailed requirements based on asserted rationales for obviousness. The Rationales To Support Rejections Under 35 U.S.C. §103 provide the following possible rationales:

(A) Combining prior art elements according to known methods to yield predictable results;

(B) Simple substitution of one known element for another to obtain predictable results;

(C) Use of known technique to improve similar devices (methods or products) in the same way;

(D) Applying a known technique to a known device (method or product) ready for improvement to yield predictable results;

(E) "Obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;

(F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; and

(G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

See MPEP 8<sup>th</sup> Edition, rev. 6, §2141.

Applicants proceed with the understanding that this rejection conforms to rationale G quoted above. The MPEP further sets forth the requirements for an obviousness rejection under this rationale:

To reject a claim based on [rationale G], Office personnel must resolve the Graham factual inquiries. Then, Office personnel must articulate the following:

(1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings;

(2) a finding that there was reasonable expectation of success; and

(3) whatever additional findings based on the Graham factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The rationale to support a conclusion that the claim would have been obvious is that “a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success.” *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1360, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006). **If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.**

See MPEP 8<sup>th</sup> Edition, rev 6, §2143.

As explained in detail above, Hanna ‘337 fails to disclose the admixture of additional antisolvent at least one second after the solution/suspension has been mixed with the first supercritical fluid and after precipitated particles have grown to a volume weighted average diameter of at least 0.1  $\mu\text{m}$ .

Applicants also respectfully note that the second supercritical fluid described in the process of Hanna ‘337 serves an entirely different purpose than the additional antisolvent described in the present process. Hanna ‘337 describes as follows:

Furthermore, the process of the present invention allows for a greatly improved dispersion of the solution or suspension of the substances of interest, by the additional impinging (preferably counter-current) flow of the second supercritical fluid. This improved dispersion can be attributed to enhanced physical contact between the solution/suspension and the (usually relatively high velocity and therefore also high kinetic energy) supercritical fluids, hence effecting the formation of very fine particles with an extremely narrow size distribution.

Col. 2, lines 16-25. In contrast, the present specification teaches :

In order to achieve uniform particle growth without significant occurrence of additional nucleation, the extra antisolvent is admixed after the precipitated particles have grown to a volume weighted average diameter of at least 0.1  $\mu\text{m}$ , preferably of at least 0.4  $\mu\text{m}$ . Generally, uniform particle growth with no additional nucleation can be achieved if the antisolvent is admixed at least 1 second after completion of step a, preferably at least 5 seconds after completion of step a.

Page 6, line 11-16. There is no motivation to alter the teachings of Hanna ‘337 because dosing so as the Examiner suggests would not result in the presently claimed process of

addition of the extra antisolvent after the precipitated particles have grown to a predetermined size.

Hanna '337 teaches utilization of the second supercritical fluid to improve dispersion of the solution or suspension of the substance, implying that the solution/suspension, first supercritical fluid, and second supercritical fluid are admixed essentially simultaneously. In contrast, the presently claimed process teaches admixing the additional antisolvent after the solution has already been dispersed into the antisolvent and after nucleation has already commenced. There would be no expectation of success in altering Hanna '337 because Hanna '337 teaches away from adding antisolvent 1 second after admixture of the solution/suspension and the first supercritical fluid.

In addition, Hanna teaches the following:

For the at least two primary nozzle passages, the outlet of an inner passage may occur either upstream or downstream of that of one or more of the surrounding outer passage(s) or at virtually the same location. In the first case, contact between a solution/suspension passing through the inner passage and a first supercritical fluid passing through a surrounding passage occurs inside the primary nozzle and before the two together contact the second supercritical fluid. Accordingly, a degree of dispersion and extraction can occur before further dispersion by the second supercritical fluid.

Col. 6, lines 57-67.

Applicants respectfully assert that the Examiner's conclusion of obviousness is based on improper hindsight reasoning in concluding that one of skill in the art would be motivated to alter the Hanna'337 reference to admix the second supercritical fluid at least 1 second after the solution/suspension has been combined with the first supercritical fluid and after the precipitated particles have grown to a volume weighted average diameter of at least 0.1  $\mu\text{m}$ . The Examiner may take into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made and not include knowledge gleaned only from applicant's disclosure. MPEP §2145. Applicants respectfully request withdrawal of the rejection.

Hanna '337 in view of Hanna '262

Claim 27 is rejected under 35 U.S.C. §103(a) as being unpatented over Hanna

'337 in view of Hanna (U.S. Patent No. 6,575,262; hereinafter "Hanna '262"). The Examiner characterizes Hanna '337 as above, and states that Hanna '337 does not teach that the particles obtained in step (c) have a particle size distribution with a standard deviation of less than 50% of the volume weighted average particle size. The Examiner contends that Hanna '262 satisfies this deficiency and thus it would be obvious to combine the references for the benefit of producing uniform solute particles. Office Action pages 8-9.

Applicants respectfully traverse the rejection. Hanna '337 is characterized above. Contrary to the Examiner's assertions, Hanna '262 does not satisfy the deficiencies of Hanna '337. There is no teaching or suggestion in Hanna '262 of the admixture of additional antisolvent at least one second after the solution/suspension has been mixed with the first supercritical fluid and after precipitated particles have grown to a volume weighted average diameter of at least 0.1  $\mu\text{m}$ . Thus, there is no motivation to combine the teachings of Hanna '337 and Hanna '262 because the combination would not result in the presently claimed process. There would be no expectation of success in combining the two references because the combination teaches away from adding antisolvent 1 second after admixture of the solution/suspension and the first supercritical fluid. Withdrawal of the rejection is respectfully requested.

Hanna '337 in view of Avontuur

Claim 28 is rejected under 35 U.S.C. §103(a) as being unpatented over Hanna '337 in view of in view of Avontuur (U.S. Patent No. 6,830,714). The Examiner characterizes Hanna '337 as above, and states that Hanna '337 does not teach that that at least 10% of the solute present in the stream of the fluid solution of step (a) is recovered in the particles obtained in step (d). The Examiner contends that Avontuur satisfies this deficiency and thus it would be obvious to combine the references for the purpose of isolating and recovering the starting solute in small, fine particles.

Applicants respectfully traverse the rejection. Hanna '337 is characterized above. It is clear that Avontuur does not cure the deficiencies of Hanna '337. Avontuur neither teaches nor suggests the admixture of additional antisolvent at least 1 second after the solution/suspension has been mixed with the first supercritical fluid and after precipitated particles have grown to a volume weighted average diameter of at least 0.1  $\mu\text{m}$ . Thus, there is no motivation to combine the teachings of Hanna '337 and Avontuur as the combination

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would not result in the presently claimed process. There would be no expectation of success in combining the two references because the combination teaches away from adding antisolvent 1 second after admixture of the solution/suspension and the first supercritical fluid. Withdrawal of the rejection is respectfully requested.

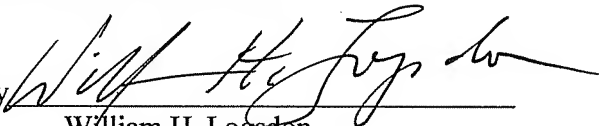
### CONCLUSION

Applicants respectfully request reconsideration and withdrawal of all rejections. An indication of allowance of all pending claims is respectfully solicited.

In the event any issues remain, Applicants would appreciate the courtesy of a telephone call to their counsel to resolve such issues.

Respectfully submitted,

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